THIS IS A SAMPLE SINGLE PROJECT ASSURANCE (SPA) FOR AN INSTITUTION WHICH CURRENTLY DOES NOT HAVE A MULTIPLE PROJECT ASSURANCE (MPA) OR SINGLE PROJECT ASSURANCE (SPA) ON FILE WITH THE OFFICE FOR PROTECTION FROM RESEARCH RISKS (OPRR) AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS).

FULL BOARD REVIEW REQUIRED OF IRB

Using this Sample, type on Institutional Letterhead supplying where indicated, information specific to the proposed research activity and your Institution, and include the required certification on the endorsement page.

(Name of Institution)

Assurance of Compliance with DOJ Regulations for
Protection of Human Research Subjects

(Name of Institution) _____, hereinafter known as the "institution", hereby gives assurance that it will comply with the Department of Justice (DOJ) regulations for the protection of human research subjects (28 CFR 46) as specified below.

PART 1

Ethical Principles and Institutional Policies Governing Research Involving Human Subjects

I. Applicability

Except for research exempted or waived under the DOJ regulations 28 CFR 46.101, Part 1 of this Assurance applies to all research involving human subjects, and all other activities which even in part involve such research, regardless of whether the research is otherwise subject to federal regulation, if:

a. the research is sponsored by this institution, or
b. the research is conducted by or under the direction of any employee or agent of this institution in connection with institutional responsibilities, or
c. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
d. the research involves the use of this institution's nonpublic information to identify or contact human research subjects or prospective subjects.

II. **Ethical Principles Governing Human Subjects Research**

This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") and as specified below.

A. This institution recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice as stated in the Belmont Report and will apply these principles in all research covered by this Assurance.

B. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

III. **Policies**

A. This institution acknowledges that it and its investigators bear full responsibility for the performance of all research covered by this Assurance, including full responsibility for complying with Federal, state, and local laws as they may relate to such research.

B. This institution assures that before human subjects are involved in research, proper consideration will be given to:

(1) the risks to the subjects,
(2) the anticipated benefits to the subjects and others,
(3) the importance of the knowledge that may reasonably be expected to result,
(4) the informed consent process to be employed,
(5) the provisions to protect the privacy of subjects, and
(6) the additional safeguards for vulnerable populations.

C. This institution recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

D. This institution encourages and promotes constructive communication among the institutional officials, research administrators, department heads, research investigators, clinical care staff, human subjects, and all other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

E. This institution will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

PART 2

IRB, Institution, and Investigator Compliance with 28 CFR 46

I. **Applicability**

Part 2 of this Assurance applies to the following research project which is conducted or sponsored by this institution and supported by the Department of Justice, Office of Justice Programs, National Institute of Justice (NIJ).

Project Title _____

NIJ Project Number _____

Project Investigator or Director _____

II. **Institutional Responsibilities**

A. This institution has complied and will continue to comply with the requirements of 28 CFR 46 as specified below.

B. In accordance with the compositional and quorum requirements of 28 CFR 46.107 and 46.108, the Institutional Review Board (IRB) designated in Part 3 and in the attached roster is responsible for the initial and continuing review of this project.

C. This institution has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and record keeping duties.

D. In addition to the review and approval of the IRB, this institution has reviewed and sponsors the project referenced above.

III. **IRB Review**

A. The IRB shall review, and have the authority to approve, require modification in, or disapprove this research activity or proposed changes in it before human subjects may be involved.

B. The convened IRB reviewed and approved the above project.

C. The IRB determined, in accordance with the criteria found at 28 CFR 46.111, and where applicable, 45 CFR 46 Subparts B, C, and D, that protections for human research subjects are adequate.

D. The IRB has the authority to suspend or terminate approval of the above referenced research in accordance with 28 CFR 46.113 for (1) non-compliance with 28 CFR 46, and this Assurance document or the IRB's requirements, and (2) for elimination of unexpected serious harm to subjects

E. The IRB has determined that legally effective informed consent will be obtained in a manner and method which meets the requirements of 28 CFR 46.116 and 46.117.

F. Certification of IRB approval, at least annually shall be submitted to the DOJ awards unit that issued the award, as a condition for receipt of funds for a non-competing continuation.

G. Continuing reviews by the IRB shall be conducted at intervals appropriate to the degree of risk, but not less than once per year (28 CFR 46.109[e]). The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or Institutional Official to consider any matter concerned with the rights and welfare of any subject.

H. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 28 CFR 46.115.

I. The IRB shall report promptly to institutional officials and the National Institute of Justice:

(1) any serious or continuing noncompliance by investigators with the requirements of the IRB,
(2) any suspension or termination of IRB approval,
(3) any unanticipated problems or injuries involving risks to subjects or others, and
(4) any changes in this research activity which are reviewed and approved by the IRB.

J. Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children in accordance with Subparts B, C, and D of 45 CFR 46. The IRB will notify National Institute of Justice promptly when IRB membership is modified to satisfy any additional requirements.

K. The IRB will comply fully with the requirements of all applicable Federal policies and guidelines, including those concerning notification of sero-positivity, counseling, and confidentiality of subjects.

IV. **Research Investigator Reporting Responsibilities**

A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance and 28 CFR 46.

B. Research investigators shall report promptly to the IRB proposed changes in this research activity and the changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.

C. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others.

PART 3

Certification of IRB Approval and Institutional Endorsement

Project Title _____
NIJ Project Number _____

Project Investigator or Director _____

Date of IRB Approval _____
Date of Next Scheduled IRB Review _____

The officials signing below assure that the project referenced above was approved by the IRB on the date indicated and that the project will be conducted in accordance with the requirements of Part 46, Title 28 of the Code of Federal Regulations and this Assurance document. A dated roster listing the current membership of the designated IRB is attached.

I. **Authorized Official of the Institution Providing This Assurance**

Signature _____ Date:_____

Please type the following items.

Name and Title:
Address:
Telephone: FAX:

II. **Authorized Official of the Institution with the IRB**
(Include only if different from the institution above)

This institution authorizes the designation of its IRB for review of the project referenced in this Assurance.

Signature _____ Date:_____

Please type the following items.

Name and Title:
Address:

Telephone: FAX:

III. **IRB Chairperson**
(Must be completed in all cases [see IRB membership list])

Signature _____ Date:_____

Please type the following items.

Name and Title:
Address:
Telephone: FAX:

MPA number if applicable _____

IV. **Responsible Project Investigator or Director at Institution Providing this Assurance**

I have attached copies of all NIJ requested and IRB approved Informed Consent Documents to be used in this project unless the designated IRB operates under an OPRR-approved Multiple Project Assurance (MPA) or unless NIJ has indicated otherwise.

Signature _____ Date:_____

Please type the following items.

Name
Title:
Address:
Telephone: FAX:

****

- SPACE BELOW FOR DOJ -

All parts of this Assurance are in compliance with the requirements of Part 46, Title 28 of the Code of Federal Regulations.

NIJ Approving Official

Signature _____ Date:_____

Name:
Address:

ASSURANCE NUMBER S-_____

An application for new or competing support for continuation in which human subjects will be involved will require a new and separate Assurance, unless the activity is exempt under section 28 CFR 46.101(b).

INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP[1]

[1] Please resubmit as changes occur.

Name of Institution Providing this Assurance:_____ Assurance Number: _____

Name of Institution with the IRB (if different from above): _____ Assurance Number:_____

Member Name	Highest Degrees Earned	Primary Scientific or Non-Scientific Speciality	Affiliation with Institution(s) Above (Yes/No; If yes, which one)
*			
#			
NV			

* Denotes Chairperson; # Denotes Alternates (If any, denote member for whom alternate will serve); NV Denotes Non-Voting Member

Address and Phone Number of IRB Chairperson_____
IRB Chair Signature:_____ Date:_____

Note: Each IRB shall include at least one member whose primary concerns are non-scientific areas, as well as one member who is not otherwise affiliated with this institution. Please review 28 CFR §46.107 for other IRB membership requirements.